Restriction Requirement

The Office Action asserts that the application contains the following groups of inventions:

Group I Claims 1-10, drawn to a method of detecting or differentiating rheumatoid arthritis or a method of determining the stage of disease with regard to rheumatoid arthritis or a method of determining the degree of dysfunction with regard rheumatoid arthritis wherein the levels of human L-PGDS in a sample collected from a subject is measured.

Group II Claims 11-14, drawn to an antibody specifically recognizing human L-PGDS for detection or differentiation of rheumatoid arthritis and for determination of the stage of the disease or the degree of dysfunction with regard to rheumatoid arthritis.

Election

In response to the requirement for restriction, Applicants elect the invention of Group I, claims 1-10, allegedly drawn to a method of detecting or differentiating rheumatoid arthritis or a method of determining the stage of disease with regard to rheumatoid arthritis or a method of determining the degree of dysfunction with regard rheumatoid arthritis wherein the levels of human L-PGDS in a sample collected from a subject is measured, with traverse. Applicants submit that claims 1-10 encompass elected Group I.

Traverse

Notwithstanding the election of Group I in order to be responsive to the requirement for election, Applicants respectfully traverse the requirement for restriction.

Applicants note that this application is a national stage application, and therefore under unity of invention practice the Examiner must establish that the claims lack unity of invention under PCT Rule 13.1 and 37 C.F.R. 1.475.

In particular, the Examiner is reminded that in determining unity of invention, the criteria set forth in 37 C.F.R. 1.475 must be considered. Specifically, Applicants note that 37 C.F.R. 1.475 provides:

> Unity of invention before the International Searching Authority, the International Preliminary Examining Authority, and during the national stage.
>
> (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
>
> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> (1) A product and a process specially adapted for the manufacture of said product; or
>
> (2) A product and process of use of said product; or
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
>
> (4) A process and an apparatus or means specifically designed for carrying out the said process; or
>
> (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
>
> (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
>
> (d) If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other

> categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
>
> (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Applicants respectfully submit that the Restriction Requirement fails to satisfy the requirements for supporting a restriction requirement under the PCT Rules. PCT Rules 13.1 and 13.2 state that an international application must relate to one invention only or, if there is more than one invention, those inventions must be so linked as to form a single general inventive concept (Rule 13.1). Inventions are considered linked so as to form a single general inventive concept only when there is a technical relationship involving one or more of the same or corresponding "special technical features." The expression "special technical features" means those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art (Rule 13.2).

Applicants note that this application is an application filed under 35 U.S.C. § 371 and that unity of invention requirements apply. The Examiner's attention is respectfully directed to MPEP 1850 and 37 CFR § 1.475, which explicitly sets forth that "[a]n international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn [] to. . .[a] process and an apparatus or means specifically designed for carrying out the said process . . . ." The claims of the present application involve a method for detecting or differentiating rheumatoid arthritis and an antibody specifically recognizing human L-

PGDS for using the claimed method. Applicants submit that the restriction requirement is deficient because it does not refer to 37 C.F.R. § 1.475.

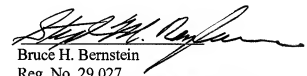
Additionally, Applicants respectfully note that the sole basis for the restriction requirement is the Office's reliance on EP 09994471 A1 to Oda et al., which the Office asserts shows that the common feature between the Groups is disclosed in the prior art. Applicants further respectfully remind the Office that, because Oda et al. is the sole basis for the Office's conclusion that a lack of unity exists, the Office will be required to withdraw its conclusion of lack of unity and examine all pending claims upon a conclusion the Oda et al. does not disclose the claimed invention or is not available as prior art. In this regard, Applicants expressly reserve the right to rebut any art-based rejections made on the basis of Oda et al., if such rejections are made.

Conclusion

For the reasons discussed above, it is respectfully submitted that the Examiner's requirement for restriction is improper and should be withdrawn. Withdrawal of the requirement for restriction with the examination of all claims pending in this application is respectfully requested. Favorable consideration with early allowance of the pending claims is most earnestly requested.

If the Examiner has any questions, or wishes to discuss this matter, please call the undersigned at the telephone number indicated below.

Respectfully submitted,
Yasuhiko SHIINA et al.



Bruce H. Bernstein
Reg. No. 29,027

Stephen M. Roylance
Reg. No. 31,296

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GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191